



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2012-F-1100]

Food Additives Permitted in Feed and Drinking Water of Animals; Benzoic Acid

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of benzoic acid as an acidifying agent in swine feed. This action is in response to a food additive petition filed by DSM Nutritional Products.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Submit either written or electronic objections and requests for a hearing by [INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]. See section V of this document for information on the filing of objections.

ADDRESSES: You may submit either electronic or written objections and a request for a hearing, identified by Docket No. FDA-2012-F-1100, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and docket number for this rulemaking. All objections received will be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting objections, see the “Objections” heading of the SUPPLEMENTARY INFORMATION section of this document.

Docket: For access to the docket to read background documents or objections received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Isabel W. Pocurull, Center for Veterinary Medicine (HFV-226), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-453-6853, isabel.pocurull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In a notice published in the Federal Register of December 4, 2012 (77 FR 71750), FDA announced that a food additive petition (animal use) (FAP 2273) had been filed by DSM Nutritional Products, 45 Waterview Blvd., Parsippany, NJ 07054. The petition proposed to amend the food additive regulations to provide for the safe use of benzoic acid as a feed acidifier in swine

feed. The notice of filing provided for a 30-day comment period on the petitioner's environmental assessment. One comment was received that was not substantive.

II. Conclusion

FDA concludes that the data establish the safety and utility of benzoic acid for use as proposed with modification and that the food additive regulations should be amended as set forth in this document.

III. Public Disclosure

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person (see FOR FURTHER INFORMATION CONTACT). As provided in §571.1(h), the Agency will delete from the documents materials that are not available for public disclosure before making the documents available for inspection.

IV. Environmental Impact

The Agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment, nor an environmental impact statement is required.

V. Objections and Hearing Requests

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see ADDRESSES) either electronic or written objections. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provision of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state.

Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection.

It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 573 is amended as follows:

PART 573--FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Add § 573.210 to read as follows:

§ 573.210 Benzoic acid.

The food additive, benzoic acid, may be safely used in the manufacture of complete swine feeds in accordance with the following prescribed conditions:

(a) The additive is used or intended for use as a feed acidifying agent, to lower the pH, in complete swine feeds at levels not to exceed 0.5 percent of the complete feed.

(b) The additive consists of not less than 99.5 percent benzoic acid (CAS 65-85-0) by weight with the sum of 2-methylbiphenyl, 3-methylbiphenyl, 4-methylbiphenyl, benzyl benzoate, and isomers of dimethylbiphenyl not to exceed 0.01 percent by weight.

(c) To assure safe use of the additive, in addition to the other information required by the Federal Food, Drug, and Cosmetic Act and paragraph (b) of this section, the label and labeling shall contain:

(1) The name of the additive.

(2) Adequate directions for use including a statement that benzoic acid must be uniformly applied and thoroughly mixed into complete swine feeds and that the complete swine feeds so treated shall be labeled as containing benzoic acid.

(3) Appropriate warnings and safety precautions concerning benzoic acid.

(4) A warning statement identifying benzoic acid as a possible irritant.

(5) Information about emergency aid in case of accidental exposure.

(6) Contact address and telephone number for reporting adverse reactions or to request a copy of the Material Safety Data Sheet (MSDS).

Dated: March 6, 2014.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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